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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
32860-001073/US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/589,560	August 16, 2006

First Named Inventor
Klaus ABRAHAM-FUCHS et al.

Art Unit	Examiner
3626	Michael Fuelling

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

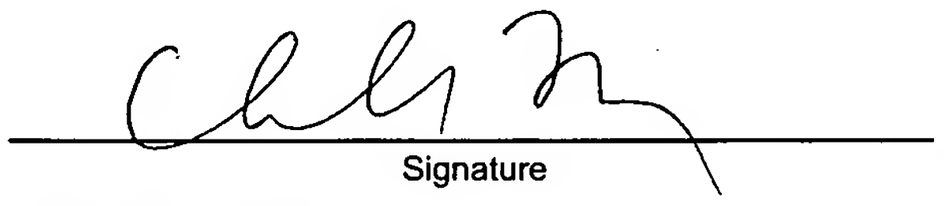
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 34,313.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Donald J. Daley
Typed or printed name

703-668-8000
Telephone number

February 10, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

PATENT
32860-001073/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANTS: Klaus ABRAHAM-FUCHS et al. CONF. NO.: 8514

SERIAL NO.: 10/589,560 GROUP: 3626

FILED: August 16, 2006 EXAMINER: Michael Fuelling

FOR: METHOD AND INFORMATION SYSTEM FOR PERFORMING A CLINICAL STUDY ON A PATIENT

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314
Mail Stop: AF

February 10, 2011

REASONS FOR PRE-APPEAL REQUEST FOR REVIEW

Dear Sir:

In response to the Office Action mailed on November 10, 2010 ("Office Action"), Applicants request that the Pre-Appeal Brief Review Panel (hereinafter Panel) review the pending rejections. The Reasons for Pre-Appeal Brief Request for Review are being filed concurrently with the Pre-Appeal Brief Request for Review and a Notice of Appeal.

Claims 1-23 are pending in the current Application, and claims 1-23 stand rejected. Claims 1, 7 and 17 are independent claims.

Initially, please see Applicants' statements set out in the Amendment filed February 9, 2011 as reflected by the Applicants' remarks beginning on page 7 with regard to the Rejections under 35 U.S.C. § 112 and §103(a). Claim 1 is a representative claim.

Applicants note, claims 1, 7, 9, 17 and 19 were amended by the Amendment filed February 9, 2011 in order to overcome the 35 U.S.C. § 112 rejections. The amendments place the application in better form for Appeal by materially reducing or simplifying the issues for Appeal.

Rejections For Which Conference Is Requested

A Pre-Appeal Brief Conference is respectfully requested to review the rejection to claims 1-23 which stand as rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,072,383 to Brimm et al. ("Brimm") in view of US Patent No. 6,168,563 to Brown ("Brown"). For the reasons detailed below, withdrawal of the current rejections is requested.

BRIMM DOES NOT TEACH OR FAIRLY SUGGEST "[A] METHOD FOR CARRYING OUT A CLINICAL STUDY INVOLVING A PATIENT."

During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Cen*ter, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). The plain meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention" (see *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Phillips also indicated that evidence for the ordinary and customary meaning of a term may be derived from "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art"

The plain meaning of a clinical study is "[a] research study used to find better ways to treat individuals with a specific disease, patients are evaluated after being administered a new drug or treatment."[1] The Examiner states "Brim does not appear to expressly use the term 'clinical study', Brim discloses a medical regimen, as

[1] See the definition of Clinical trial as defined in McGraw-Hill Dictionary of Scientific and Technical terms, Sixth Edition, pg. 407.

described above, and a clinical study is a medical regimen. Further, applicant's use of the term 'clinical study' merely is a nonfunctional description of the data."[2]

Clearly, a research study is not a medical regimen as asserted by the Examiner. Brimm at most concerns an automated clinical records management system. Such system has utility, for example, in a hospital-based patient record-keeping system. Patient record-keeping systems are used for maintaining a wide variety of types of medical records concerning clinic or hospital patients. See Brimm column 1, lines 42-47. A medical regimen, as described by Brimm, relates to normal patient care as administered by a hospital. The clinical records of Brimm closely resemble manual clinical records. See Brimm column 4, lines 10-15.

Further, the term clinical study is not a nonfunctional description of the data. A clinical study is a term of art. As a result, the Examiner is required to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

For at least the above reasons, Brimm does not teach or fairly suggest "[a] method for carrying out a **clinical study** involving a patient," as required by claim 1.

BRIMM DOES NOT TEACH OR FAIRLY SUGGEST "STORING ON A MEMORY, STUDY-RELATED DATA ASSOCIATED WITH A PROTOCOL OF THE CLINICAL STUDY,"

As described above, Brimm does not disclose a clinical study. Consequently, Brimm has no reason to store "study-related data associated with a protocol of the clinical study," as required by claim 1. By contrast, Brimm stores physician orders, e.g. medication orders, lab orders, radiology orders, consultant orders (e.g. relating to

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[2] See Office Action dated November 10, 2010, pg. 5.

care to be provided by other physicians) and orders relating to nutrition, psychiatric care, general health, etc. See Brimm column 9, lines 1-6. Brimm discloses storing physician orders associated with normal patient care. Brimm is silent with regard to clinical studies and protocols associated therewith.

For at least the above reasons, Brimm does not teach or fairly suggest storing on a memory, study-related data associated with a protocol of the clinical study," as required by claim 1.

BRIMM DOES NOT TEACH OR FAIRLY SUGGEST "STORING, ON THE MEMORY, PATIENT-RELATED DATA ASSOCIATED WITH THE PATIENT AND THE CLINICAL STUDY,"

As described above, Brimm does not disclose a clinical study. Consequently, Brimm has no reason to store "patient-related data associated with the patient and the clinical study," as required by claim 1. By contrast, Brimm records medications (or other care events) given to the patient as ordered by the physician. See Brimm column 9, line 64 to column 10, line 15.

Brown does not disclose the aforementioned limitations and the Examiner does not rely on Brown to disclose the aforementioned limitations.

For at least the reasons described above, Brimm and Brown, alone and in combination (assuming *arguendo* that Brown could be combined with Brimm, which the Applicants do not admit) do not teach each and every limitation of claims 1, 7 and 17. Because Brimm and Brown do not teach or fairly suggest each and every limitation of independent claim 1, Brimm in view of Brown does not render claim 1 obvious. Claims 7 and 17 are patentable for reasons at least somewhat similar to those discussed above with regard to claim 1, noting that claims 7 and 17 should be

interpreted solely based on the limitations set forth therein. Claims 2-6, 8-16 and 18-23 are patentable at least by virtue of their dependency from an independent base claim.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-23 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the remarks, reconsideration of the objections and rejections and allowance of each of the pending claims in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Pre-Appeal Brief Review Board is respectfully requested to contact the undersigned at the telephone number. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, PLC

By _____

Donald J. Daley, Reg. No. 34,313

P.O. Box 8910
Reston, VA 20195
(703) 668-8000

DJD/EPS:lfb

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